

REMARKS

Status of Claims

Claims 1-21, 23-37, 44-45, 47-80, and 85-91 were pending. By this Amendment, claims 1, 6, 9, 10, 14, 21, 48, 49, 52, 86-88, and 91 are amended, claims 5, 50, and 51 are canceled, and new claims 92-93 are presented. No new matter is entered.

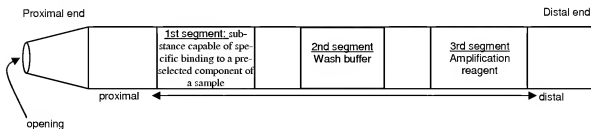
Claim Rejections: 35 U.S.C. § 102

Claims 1, 2, 5-10, 14-16, 23, 29-32, 36-37, 45, 76, 77, and 85-91 were rejected under 35 U.S.C. § 102(b) as reciting subject matter anticipated by U.S. Pat. No. 5,422,271 to Chen et al.

Applicants ask the Examiner to reconsider and withdraw the rejection because Chen does not disclose the arrangement of claim 1.

Claim 1 recites a sample processing tubule having a proximal end and a distal end. The proximal end has an opening through which a sample is introducible. The tubule also has first, second, and third segments. The third segment is distal to the second segment, and the second segment is distal to the first segment. Put another way, the first segment is proximal to the second segment, and the second segment is proximal to the third segment. The claim further specifies contents of each segment. The first segment contains at least one substance capable of specific binding to a preselected component of a sample; the second segment contains a wash buffer, and the third segment contains an amplification reagent.

So a tubule of claim 1 can be represented diagrammatically as follows:



Chen, in contrast, consistently and exclusively describes devices in which the amplification reagents are upstream of all other reagents. Chen's amplification reagents

are in “PCR reaction compartment 26” in Fig. 1 and in 26a, 26b, and 26c in Figs. 2, 3, and 7, respectively. The PCR reaction compartment is *always* the first compartment immediately downstream of the inlet port 22, 22a, 22b. And indeed it has to be so for Chen’s device to work; Chen expressly states that *amplified* nucleic acid material is advanced to site 41 *before* the SA-HRP label (see Chen col. 4, lines 65-67: “the respective sequential movements of the amplified nucleic acid material and the SA-HRP, to sites 41...”

It would make no sense to place amplification reagents downstream of the SA-HRP label, so that the SA-HRP is part of the amplification mixture, for at least two reasons: (a) the SA-HRP would immediately bind to the primer, thus instantly labeling all primers (which are biotinylated) and sterically hindering them from binding the DNA template during PCR; and (b) the SA-HRP (a temperature-sensitive enzyme) would be inactivated by the 95°C denaturation step in PCR. Instead, Chen first performs PCR in compartment 26, then advances roller 60 over the cassette, which pushes amplification product into the binding zone, followed by a label (SA-HRP) from compartment 30, an optional wash from compartment 32, and finally dye (HRP substrate) from compartment 34.

So not only does Chen fail to teach an amplification reagent in a distal segment, he affirmatively teaches away from such a modification. Chen thus does not disclose the claimed arrangement of segments in claim 1 and discourages the reader from the claimed arrangement.

Claim Rejections: 35 U.S.C. § 103(a)

Claims 3 and 24-28 were rejected under 35 U.S.C. § 103(a) as encompassing subject matter unpatentable over Chen et al. 5,422,271 in view of Chen et al. US-2003/0049833-A1.

But Chen ’833 was published on Mar. 13, 2003, after the present application’s priority date of Feb. 5, 2003 (filing date of provisional application ser. no. 60/445,304). Applicants’ priority claim is effective for the rejected claims; see, for example, Fig. 4 and claim 3 on p. 75, disclosing a pressure gate, and Figs. 1, 3, and 4 and claims 1 and 16-19 on pp. 77-76 disclosing the claimed caps.

Chen '833 is therefore citable only under 35 U.S.C. § 102(e). But the present application and Chen '833 were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same or organization, namely, IQuum, Inc. Chen '833 was assigned to IQuum, Inc. by assignment recorded at Reel/Frame 013483/0078, and the present application was assignment to IQuum, Inc. by assignment recorded at Reel/Frame 014974/0238.

Chen '833 is therefore disqualified as prior art against the present application under 35 U.S.C. § 103(c)(1). *See* M.P.E.P. § 706.02(l)(3).

Claims 4, 17, and 18 were rejected under 35 U.S.C. § 103(a) as encompassing subject matter unpatentable over Chen et al. 5,422,271 in view of Presnell et al. US-2003/0134390-A1.

Claims 44, 47, and 78-80 were rejected under 35 U.S.C. § 103(a) as encompassing subject matter unpatentable over Chen et al. 5,422,271 in view of Miethe et al. 6,488,894.

But neither Presnell nor Miethe overcomes Chen's deficiencies; Chen is fundamentally incompatible with the claimed arrangement because he absolutely requires that amplification reagent be positioned in the most proximal compartment. So Chen teaches away from the claimed arrangement, regardless of whatever other reference with which it might be combined.

Conclusion

Applicants ask the Examiner to reconsider and withdraw every rejection for these reasons.

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Respectfully submitted,

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